

Medical Research Council comments on outline for the revision of Directive 86/609 on the protection of animals used for experimental and other scientific purposes, Jan 2007

1. GENERAL COMMENTS

We have been invited by the European Coalition for Biomedical Research, the Bioscience Federation, and the Office of Science and Innovation to comment on the outline for the revised Directive (dated 18 January 2007). This note summarises the MRC's response. We have discussed our comments with BBSRC, but owing to pressure of time are submitting our views separately.

As drafted, the revised Directive, in using words like "as a minimum", is likely to encourage some Member States to impose more onerous regulations than necessary to assure animal welfare, while allowing other States to specify significantly lighter controls. This will run counter to the EU policy of promoting harmonisation.

There are some proposed controls (referred to below) that add bureaucracy without evidence of any expected associated gain in animal welfare. As well placing the speed of the EU's scientific progress at risk, these unnecessary controls could put the countries of the EU at a competitive disadvantage with other nations. Any controls required by the revised Directive should be proportional to their potential to improve animal welfare.

2. ETHICAL EVALUATION OF PROJECTS

We welcome the idea of using a non-technical ('lay') summary of the proposals to improve transparency, to be revised if necessary during the ethical evaluation and made publicly available once projects are authorised. (See section 3 below.)

Retrospective evaluation would be introduced based on a risk assessment at ethical evaluation. The Commission proposes that the lay summary would have to identify whether a project was to undergo such a retrospective evaluation. We have reservations about flagging this before the evaluation has taken place.

We had some difficulty understanding how one could quantify non-mathematically. (clause 3 of Annex VII).

3. PROJECT AUTHORIZATION

Project authorisation

We would support the publication of 'lay' summaries of authorised projects, subject to safeguarding confidential information (personal and commercial). The draft refers to 'lay' summaries in relation to ethical approval and project authorisation. We assume, indeed would expect, that what was finally published would be a single 'lay' summary incorporating any final amendments made as part of project authorisation.

The upper limit on the duration of authorisations should be 5 years, not the 3 years proposed. A shorter period would increase bureaucracy with no evidence of associated animal welfare benefits.

We support the proposed exemptions from project authorisation, but suggest that further consideration is needed to exemptions from personal authorisation (see section 11 below).

4. AUTHORISATION OF ESTABLISHMENTS

Provisions with regard to animal welfare in establishments

Much of what the Commission proposes appears to be covered already in UK regulations. However, the idea of annual review of 'multi-annual projects' is a step beyond current requirements. With the possible exception of annual reporting on highly sensitive work, e.g. research in the 'severe' band, there is no clear welfare value of such reporting, in addition to final reporting at the end of a project.

The provisions in section 1 e) on factors that must be reviewed annually are excessively detailed and, in themselves, confer no clear animal welfare benefit. The preceding section d) covers the key issue; the detail in e) includes aspects already addressed adequately in the original ethical review.

Inspections

We agree with the value of a proportional approach. However, the draft Directive calls for a minimum of two inspections per year of which one should be unannounced (with more frequent visiting based on a risk assessment). A bi-annual visit to all establishments, irrespective of the number or nature of the projects, would be excessive. 'Frequency' is, anyway, less relevant a concept than 'extent'.

5. AUTHORISATION OF PERSONS

We welcome the emphasis in the revised Directive on the quality of education and training, and on the acquisition, demonstration and maintenance of competence. However, some of the training should be proportional to the duration and severity of the animal work to be undertaken (recognising the need for core training common to all). In addition, exemptions should be available for those with prior appropriate training e.g. veterinarians, or experienced scientists visiting from non-EC countries.

6. TRANSPARENCY AND PUBLIC ACCESS TO INFORMATION

The MRC supports the Commission's aspirations, so long as the provisions do not impose a bureaucratic burden out of proportion to any benefits. However, it is important that the 'lay' summaries are anonymised to safeguard individuals and institutions, and are allowed to exclude information that is commercially sensitive or which could lead to the identification of the researchers.

7. SEVERITY AND RE-USE

Severity of procedures

We would support a cross-EU approach to developing guideline on how severity classes are to be assigned. Leaving this to Member States risks creating a series of conflicting approaches, that would undermine any attempt to understand the pattern of procedure severity across the EU.

Re-use

The Commission proposal that animals may only be re-used once is well-intentioned but misguided. There are several situations where such a policy would harm animal welfare. For instance, it would prevent an animal being used as a control in several experiments where no distress occurred, so increasing the number of animals used. Species such as frogs are often re-used several times for egg collection without any significant welfare issues. In primates, initial training may be the most stressful phase, not the subsequent experimental 'procedure' itself.

8. NON-HUMAN PRIMATES

We welcome the Commission's acceptance that research involving non-human primates (NHPs) is still needed, while supporting the Commission's wish to encourage the finding of alternatives and ensure the highest achievable welfare. The MRC has no objections to the main requirement that use should be restricted to NHPs of the F2 generation (or beyond). However, we recognise that this is not a universal view.

The MRC agrees with the view in the consultation that at present great apes should not be used for research, but we would advise that their possible future use should not be prohibited in law.

9. PROMOTION OF ALTERNATIVE APPROACHES

The preliminary draft text on requirements is muddled and potentially contradictory.

The draft text currently states that: the Commission and Member States shall allocate X % of the annual national and Community research budget for the development and validation of alternative approaches. We believe that such a target is neither appropriate nor meaningful. Does the research budget include private sector research expenditure for instance? Such research is difficult to define precisely and it seems unlikely that consensus could be reached throughout the EU. Would a realistic percentage be so low as to be politically unacceptable?

We welcome other aspirations to promote the development and acceptance of new regulatory test methods, based on the 3Rs.

10. HOUSING AND CARE

The Directive is likely to require compliance with the Council of Europe's minimum standards on housing and care of animals adopted in June 2006. The UK has already signed up to these standards. However, the Commission should accept that a reasonable transition period, perhaps of at least five years, will be required to allow existing facilities to be brought into line. There is currently no mention of this in the text we have seen.

11. SCOPE

We disagree with the proposal to broaden the scope of the revised Directive to encompass animals killed humanely for the primary purpose of using their tissue and/or organs. It is unclear what would be gained in animal welfare terms. We would urge that the Commission make an exemption for such animals from most aspects of the Directive (but not from expectations that such animals are be housed and cared for to the same standards as other animals.)

The Commission proposes also to broaden coverage to include certain species of invertebrates as well as earlier life stages. We cannot comment in detail at this stage as the relevant Annex is yet to be drafted. However, apart from one invertebrate species (*Octopus vulgaris*), this is not consistent with current UK legislation, and there would need to be powerful scientific arguments if we were to support any such changes. We thus welcome the proposal to update the Annex as new scientific knowledge emerges.

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On behalf of the Medical Research Council

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